<u>REMARKS</u>

Applicant appreciates the time taken by the Examiner to review Applicant's present application. This application has been carefully reviewed in light of the Official Action mailed December 9, 2008. This Reply encompasses a bona fide attempt to overcome the rejections raised by the Examiner and presents amendments as well as reasons why Applicant believes that the claimed invention, as amended, is novel and unobvious over the applied prior art. Applicant respectfully requests reconsideration and favorable action in this case.

Claims Status

Claims 1-59, 74-75, 86-88, 96 and 97 were pending in the application. To expedite the prosecution and place the present application in a condition for allowance, claims 9, 14, 18-19, 24, 40, 43, and 55-56, and withdrawn claims 59, 74-75, and 86-88 are cancelled herein without prejudice or disclaimer. Claims 1-5, 7-8, 12, 20-23, 33, 36, 39, 42, 49, 50-52, and 57 are amended herein. Support for the amendments to the claims can be found at least from Figures 1-3, page 7, lines 15-19, and page 8, lines 6-9. By this Amendment, claims 1-8, 10-13, 15-17, 20-23, 25-39, 41-42, 44-54, 57-58, and 96-97 are pending.

Interview Summary

Pursuant to Applicant Initiated Interview Request submitted on February 3, 2009, a telephonic interview was conducted on February 18, 2009 between Examiner David Comstock, Attorney Katharina Schuster and Agent Kevin Gust. During the interview, Applicant's representatives presented the context of the claimed invention and discussed structural differences between embodiments of the claimed invention and the cited prior art. Examiner Comstock indicated that adding structural differences to the claims might overcome the cited prior art. To expedite the prosecution of the present application, independent claims 1, 36, and 49 are amended herein accordingly. Applicant appreciates the time and effort taken by Examiner Comstock to review Applicant's present application and discuss the pending claims and the cited prior art.

Rejections under 35 U.S.C. § 103

Claims 1-15, 18-58, 96 and 97 were rejected under 35 U.S.C. § 103(a) as being unpatentable over U.S. Patent No. 6,245,108 ("Biscup") alone or, in the alternative, in view of U.S. Patent No. 6,468,311 ("Boyd"). The rejection is traversed. Independent claims 36 and 49 contain similar language as claim 1. Accordingly, the traversal will be collectively addressed as it pertains to claim 1.

Although itself has no force of law, the M.P.E.P. restates the following law: The rationale to support a conclusion that the claim would have been obvious is that all the claimed elements were known in the prior art and one skilled in the art could have combined the elements as claimed by known methods with no change in their respective functions, and the combination yielded nothing more than predictable results to one of ordinary skill in the art. KSR, 550 U.S. at _____, 82 USPQ2d at 1395; Sakraida v. AG Pro, Inc., 425 U.S. 273, 282, 189 USPQ 449, 453 (1976); Anderson's-Black Rock, Inc. v. Pavement Salvage Co., 396 U.S. 57, 62-63, 163 USPQ 673, 675 (1969); Great Atlantic & P. Tea Co. v. Supermarket Equipment Corp., 340 U.S. 147, 152, 87 USPQ 303, 306 (1950). "[I]t can be important to identify a reason that would have prompted a person of ordinary skill in the relevant field to combine the elements in the way the claimed new invention does." KSR, 550 U.S. at _____, 82 USPQ2d at 1396. If any of these findings cannot be made, then this rationale cannot be used to support a conclusion that the claim would have been obvious to one of ordinary skill in the art. See M.P.E.P. 2143.

Furthermore, MPEP 2143.01 VI states, "If the proposed modification or combination of the prior art would change the principle of operation of the prior art invention being modified, then the teachings of the references are not sufficient to render the claims *prima facie* obvious. *In re Ratti*, 270 F.2d 810, 123 USPQ 349 (CCPA 1959)."

It is respectfully submitted that not all the claimed elements were known in the prior art. It is further respectfully submitted that one skilled in the art could not have combined the elements as claimed by known methods with no change in their respective functions.

Claim 1, as amended, recites:

A spinal implant, comprising:

a top, wherein at least a portion of the top is shaped to contact a first vertebra;

a bottom, wherein at least a portion of the bottom is shaped to contact a second vertebra;

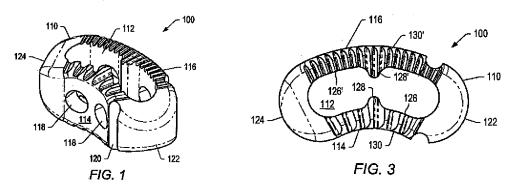
an anterior side having:

a first curvature between a distal end and a proximal end; and a first groove near said proximal end and extending from said top to said bottom; a posterior side having:

a second curvature between said distal end and said proximal end; and a second groove near said proximal end and extending from said top to said bottom, wherein said first groove and said second groove are located substantially equidistant from said proximal end, wherein the first curvature and the second curvature are substantially in the same direction;

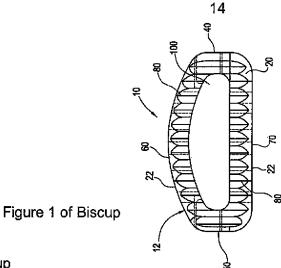
an opening extending through the spinal implant from the top to the bottom.

Thus, embodiments of a spinal implant (100) may include a top and a bottom for contact with adjacent vertebrae, a curved anterior side (116) having a first curvature, a curved posterior side (114) having a second curvature that is substantially in the same direction as the first curvature, a distal end (124), two grooves (120), a proximal end (122), and an opening (112) through the spinal implant from the top to the bottom. Figures 1 and 3, which depict views of one embodiment, are reproduced below for the convenience of the Examiner.



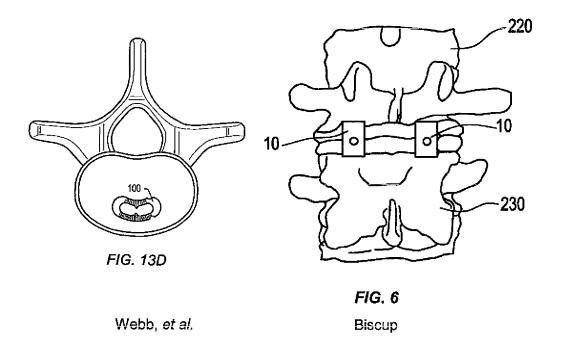
Figures 1 and 3 from Webb et al.

Biscup describes a spinal fusion implant (10) in which a cage-like structure (12) has a top wall, a bottom wall, a front end wall (40), a back end wall (50), a first side wall (60) and a back side wall (70) and an opening (100) from the top wall to the bottom wall. Figure 1, which depicts a top view of one embodiment of Biscup, is reproduced below. Figure 1 of Biscup is rotated 90 degrees to illustrate how the spinal fusion implant of Biscup is to be inserted in the patient, as discussed below.



I. Biscup

In the rejection, the Examiner states that Biscup discloses a spinal implant having a curved anterior side and a curved posterior side. Applicant respectfully submits that the device described by Biscup is for bilateral placement in the spine and that a modification of Biscup's spinal fusion implant would change the principle of operation of the device. For example, Figure 13D of the present application shows a spinal implant (100) centered about the midline of the spine. However, Figure 6 of Biscup shows two devices (10) positioned on either side of the spine.



Embodiments of a spinal implant as claimed in the present application can be placed/ inserted in an intervertebral disc space using a minimally invasive approach or a traditional

surgical approach (e.g., transverse, posterior, anterior) such that the curved anterior side would proximate the curved anterior side of the vertebrae. (See, specification, Figures 13A-13C and pg. 18, lines 4-26.) In contrast, Figure 6 of Biscup shows that implants 10 of Biscup are positioned bilaterally to the midline of the spine. Furthermore, Biscup describes using two spinal fusion implants to separate and support two vertebrae. (See, Biscup, Figure 6 and Col. 10, lines 13-24 and 48-50.) Thus, front end wall 40 and back end wall 50 of implants 10 of Biscup would end up proximate the anterior side and posterior side of the spine.

Furthermore, front side wall 60 and back side wall 70 of implants 10 of Biscup are shaped so that implants 10 of Biscup can be used with a modular component that can be attached and assembled between two implants to create a construct (ALIF type) cage. For example, implants 10 of Biscup may be attached to the modular component with back side walls 70 facing each other. Inserting a single implant 10 of Biscup sideways so that either front side wall 60 or back side wall 70 would proximate the anterior side or posterior side of the spine would have eliminated this mode of operation of Biscup or at least changed the function of Biscup.

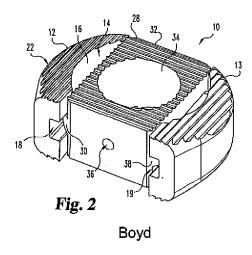
Moreover, in order for a single implant 10 of Biscup to stabilize the spine, it appears that substantial modifications might be necessary, taking into consideration that contact with the spinal cord must be avoided, that one side of implant 10 might be higher than the other side, and that implant 10 might slip or withdraw from the intervertebral disc space after insertion. Applicant believes that any such modification would change the principle of operation of Biscup. Since the proposed modification of Biscup would change the principle of operation of Biscup, Applicant respectfully submits that the teachings of Biscup are not sufficient to render the claims *prima facie* obvious.

II. Biscup in view of Boyd

In the rejection, the Examiner states that, in the alternative, claims 1-15, 18-58, 96 and 97 were rejected under 35 U.S.C. § 103(a) as being unpatentable over Biscup in view of U.S. Patent No. 6,468,311 ("Boyd"). The rejection is traversed.

Boyd describes a modular interbody fusion implant (10) which includes a connecting member (28) and a pair of lateral spacers (12 and 13). Boyd describes the lateral spacers as having a lateral side 22 which is opposite the medial side (14), and teaches that the term

"lateral" refers to the lateral portion of the spine and the term "medial" refers to the medial portion of the spine. (See, Boyd, Col. 4, lines 42-53.) Thus, it appears as though Boyd teaches that the lateral spacers are positioned in the spine and that the curvatures of the lateral sides are just that – on the lateral sides. Figure 2 of Boyd is reproduced below for the convenience of the Examiner.



In the rejection, the Examiner states that it would have been obvious to have provided the implant of Biscup with curved sides so as to be substantially kidney-shaped in view of Boyd. Applicant respectfully submits that combining Biscup and Boyd does not result in a device containing the functionality of embodiments as claimed. For example, as submitted above, Biscup describes two spinal fusion devices positioned bilaterally on either side of the spine, and Boyd goes further and describes a device constructed from three elements. Thus, it appears that the combination of Biscup and Boyd would result a device assembled from many components. Furthermore, both Biscup and Boyd teach that the curved elements are curved on the lateral sides and not the anterior/posterior sides. Applicant respectfully submits that the proposed modification or combination of Biscup and Boyd would change the principle of operation of Biscup, Boyd, or both.

For at least the foregoing reasons, Applicant submits that the teachings of Biscup and Boyd are not sufficient to render the claims *prima facie* obvious. Accordingly, withdrawal of this rejection is requested.

Claims 16 and 17 were rejected under 35 U.S.C. § 103(a) as being unpatentable over Biscup in view of Boyd and further in view of U.S. Publication No. 2005/004671 ("Ross"). The rejection is traversed.

If an independent claim is nonobvious under 35 U.S.C. 103, then any claim depending therefrom is nonobvious. *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988). As submitted above, independent claim 1 recites subject matter not reached by the combination of Biscup and Boyd under 35 U.S.C. 103(a). Claims 16 and 17 depend from claim 1 and therefore should also be allowed. Accordingly, withdrawal of this rejection is requested.

Conclusion

Applicant has now made an earnest attempt to place this case in condition for allowance. Other than as explicitly set forth above, this reply does not include any acquiescence to statements, assertions, assumptions, conclusions, or any combination thereof in the Office Action. For the foregoing reasons and for other reasons clearly apparent, Applicant respectfully requests full allowance of claims 1-8, 10-13, 15-17, 20-23, 25-39, 41-42, 44-54, 57-58, and 96-97. The Examiner is invited to telephone the undersigned at the number listed below for prompt action in the event any issues remain.

The Director of the U.S. Patent and Trademark Office is hereby authorized to charge any fees or credit any overpayments to Deposit Account No. 50-3183 of Sprinkle IP Law Group.

Respectfully submitted,

Sprinkle IP Law Group Attorneys for Applicant

athanin Schust,

Katharina W. Schuster Reg. No. 50,000

Date: February <u>4</u>, 2009

1301 W. 25th Street, Suite 408

Austin, TX 78705 Tel. (512) 637-9220 Fax. (512) 371-9088